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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

First Named Applicant: Walker	)	Art Unit: 3763
Serial No.: 09/939,239	)	Examiner: Desanto
Filed: August 24, 2001	)	001/017 (1-3) USA
	)	February 10, 2005
	)	750 B STREET, Suite 3120
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SUPPLEMENTAL APPEAL BRIEF

Commissioner of Patents and Trademarks
Washington, DC 20231

Dear Sir:

This brief is submitted in response to the attempt to reopen prosecution dated January 26, 2005. The appeal is reinstated. All fees have been paid, so no new fees are due. The appeal is under 35 U.S.C. §134 and is in accordance with 37 C.F.R. Parts 1, 5, 10, 11, and 41, effective September 13, 2004 and published at 69 Fed. Reg. 155 (August 2004).

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(1) Real Party in Interest

The real party in interest is Alsius Corp.

(2) Related Appeals/Interferences

No other appeals or interferences exist which relate to the present application or appeal.

(3) Status of Claims

Claims 5-8 and 22-34 are pending and finally rejected, Claim 38 (referred to by the Examiner as Claim 39) has been restricted out, and the remaining claims have been cancelled.

(4) Status of Amendments

No amendments are outstanding.

(5) Concise Explanation of Subject Matter in Each Independent Claim, with Page and Figure Nos.

As an initial matter, it is noted that according to the Patent Office, the concise explanations under this section are for Board convenience, and do not supersede what the claims actually state, 69 Fed. Reg. 155 (August 2004), see page 49976. Accordingly, nothing in this Section should be construed as an estoppel that limits the actual claim language.

Claim 5 recites a central venous line catheter (reference numeral 20, page 7, first paragraph of detailed description, Figure 1) having at least one substantially elongate structure (id. and page 8, second paragraph and Figures 2-5) configured for establishing central venous access. The structure has a proximal portion and a distal portion and defines at least a first lumen (e.g., 32, Figures 3 and 4, page 10, first paragraph) in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element (24, Figures 1-4, page 8 starting with last four lines) extending at least along the distal portion and adapted to effect heat exchange with the central venous system. The catheter is manufactured by flushing the first lumen from its distal portion to its proximal portion with sterile saline.

The page and figure references above are incorporated into this paragraph. In Claim 22, a venous line catheter system (10, figure 1, pages 7-8) has a catheter having at least one substantially elongate structure configured for establishing central venous access. The structure has a proximal portion and a distal portion and defines at least a first lumen in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element extending at least along the distal portion adapted to effect heat exchange with the central venous system. Unlike the invention of Claim 5, in Claim 22 a pump (in the module 50, figure 1, page 12 at bottom) feeds a heating/cooling agent at a flow rate in a range of 150 – 450 milliliters per minute through the heat exchange element (original Claim 22).

(6) Grounds of Rejection to be Reviewed on Appeal

(a) Claims 5-8 have been rejected under 35 U.S.C. §102 as being anticipated by Williams et al. (USPN 4,941,475).

(b) Claims 5-8 have been rejected under 35 U.S.C. §102 as being anticipated by Bresnaham et al. (USPN 6,117,105).

(c) Claims 5-8, 22-27, and 31-34 have been rejected under 35 U.S.C. §103 as being unpatentable over Williams et al. in view of Loubser (USPN 6,110,139).

(d) Claims 5-8 and 22-34 have been rejected under 35 U.S.C. §103 as being unpatentable over Bresnaham et al. in view of Loubser.

(7) Argument

As an initial matter, it is noted that according to the Patent Office, a new ground of rejection in an examiner's answer should be "rare", and should be levied only in response to such things as newly presented arguments by Applicant or to address a claim that the examiner previously failed to address, 69 Fed. Reg. 155 (August 2004), see, e.g., pages 49963 and 49980. Furthermore, a new ground of rejection must be approved by the Technology Center Director or designee and in any case must come accompanied with the initials of the conferees of the appeal conference, id., page 49979. The same philosophy would seem to hold true for reopening prosecution after an appeal brief is filed.

Claims 5-8 have been rejected under 35 U.S.C. §102 as being anticipated by both Williams et al. and Bresnaham et al. It is noted that the citation to the "entire reference" for each of the above-mentioned references in support of the rejections renders analysis of what the examiner is thinking problematic, and in any case is contrary to the guidance of MPEP §706.02(j) (the Examiner should set forth (1) the relevant

teachings of the prior art relied upon, preferably with reference to the relevant column or page number(s) and line number(s) where appropriate...)

The allegation that Williams et al. is a "venous line catheter" is contrary to MPEP §2111.01 (terms must be construed as the skilled artisan construes them), because Williams et al. is placed in the heart to measure cardiac output, and no evidence exists of record that the skilled artisan regards heart-dwelling cardiac output measuring catheters as "venous lines". This observation previously has elicited the retort that "any catheter has the ability to be used as a venous catheter". In and of itself, that response merits reversal. It is facially wrong. Any catheter CANNOT be used as central venous line catheter, nor would the skilled artisan (a doctor) confuse a cardiac output catheter such as the one disclosed in Williams et al. (which, when positioned, must have its operative portion in the arterial system, not the venous system, in order to work) with a central line. It is legal error to impute such faulty education in catheter types to the skilled artisan. Simply put, Claim 5 requires a structure - a central venous line catheter - that Williams et al. manifestly would not be considered to be by the skilled artisan, see MPEP §2111.01.

The allegation that Bresnaham et al. is a central venous line catheter is even further off base. Bresnaham et al. is placed in the ***arterial*** system during bypass surgery for perfusion of substances such as heart-stopping drugs. Is it seriously the examiner's position that the skilled artisan would think that Bresnaham et al. is a central venous catheter?

Note that "central venous catheter" is no mere intended use. Claim 5 ties this recitation to specific structure, i.e., an elongate structure configured for establishing central venous access.

Furthermore, the anticipation rejections of Claim 5 are contrary to MPEP §2131 and consequently must be withdrawn because they fail to mention the limitation of Claim 5 that the catheter is manufactured

by flushing the first lumen (as recited, this is an infusion lumen since it terminates at the exterior of the catheter) from its distal portion to its proximal portion with sterile saline. This is a structural limitation, since it means that residual salt remains in the lumen. This previously has been met with the argument that "applicant is reading limitations from the specification into the claims", because "there is no limitation that describes salt being left on the catheter".

It should be noted that Appellant is not here relying on a bare product-by-process limitation. Rather, anything flushed with salt cannot help but have at least some amount of residual salt on it, whether residual salt is claimed or not. In effect, the product-by-process limitation cannot but require a structure - a catheter with residual salt in a lumen - that is not present in the relied-upon references. Note further that the only place Bresnaham et al. mentions saline is in relation to inflating the occlusion balloon, not in any infusion context.

Turning to Claim 22, among other things, Claim 22 requires a "pump feeding heating/cooling agent at a flow rate in a range of 150 – 450 milliliters per minute ***through the heat exchange element.***" Appropo the rejection based on Bresnaham et al. and Loubser, in both of the references the only pumps mentioned are for fluid infusion. No mention is made of any particular pump in Bresnaham et al. for inflating its occlusion balloon. So while the examiner is correct that Bresnaham et al. and Loubser both use pumps, he (and his SPE, who signed the latest Office Action) miss the point that even if Bresnaham et al. were to be modified per the Loubser pump, it would not be for inflating the relied-upon occlusion balloon of Bresnaham et al. (much less for cycling coolant through a heat exchange element as claimed), but for what both references teach about their pumps, namely, perfusion of substances for heart surgery.

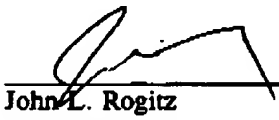
Considering the obviousness rejection of Claim 22 based on Williams et al. and Loubser, as stated above the relied-upon Loubser pump is not for inflating or circulating anything, but for one-way perfusion of drugs into the bloodstream. There is no suggestion that the relied-upon flow rate of the Loubser pump, or even the Loubser pump itself, is appropriate for circulating coolant into the cardioplegia balloon of Williams et al., because perfusion of drugs into the bloodstream for bypass surgery (the purpose of the Loubser pump) is an entirely different goal requiring entirely different flow considerations than circulating coolant into a cardioplegia balloon to measure cardiac output (Williams et al.)

In addition to the apples and oranges problem with the rejection, Appellant notes that Williams et al. nowhere discusses a particular coolant flow rate. The only place Williams et al appears to discuss flow rate at all is in the context of some hypothetical cardiac output calculations (blood flow rates) calculated by its cardioplegia system, col. 13, lines 24-33. There is thus no teaching or suggestion in any proferred reference that a cardiopulmonary bypass pump used for perfusion of substances into the blood is an appropriate instrument for circulating coolant into a cardioplegia balloon, much less that a pump flow rate for perfusing drugs into the blood during bypass surgery is a good flow rate to use for the entirely different purpose of coolant circulation performed to measure cardiac output by thermodilution.

The original brief observed that no mention had been made of the majority of the dependent claims, much less has it been identified where their respective limitations appear in the relied-upon references despite repeated chances on the part of the examiner to do so. The latest attempt to reopen prosecution is no less deficient. For instance, despite repeated requests to discuss why, precisely, the explicit and precise limitations of Claim 8 (injection caps), Claim 24 (temperature of the heating agent is between 38°C and 43°C), Claim 25 (temperature of the cooling agent is between 1°C and 5°C), Claim 27 (balloon length is

about 55-60 mm), Claim 30 (three balloons disposed in a consecutive order with specific balloon diameters), Claim 31 (specific wall thickness), and Claim 33 (specific heat conductivity of balloon) are being rejected, these claims remain rejected without discussion, ***after SPE review and approval of the present Office Action***. Having forced the present appeal after issuing multiple rejections, it would be exasperating and unacceptable indeed to cascade prosecution costs by reopening prosecution or otherwise contesting the patentability of these claims.

Respectfully submitted,



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APPENDIX A

5. A central venous line catheter, said catheter having at least one substantially elongate structure configured for establishing central venous access, said structure having a proximal portion and a distal portion and defining at least a first lumen in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element extending at least along the distal portion adapted to effect heat exchange with the central venous system, characterized in that the catheter is manufactured by flushing the first lumen from its distal portion to its proximal portion with sterile saline.

6. The catheter of claim 5, characterized in that the volume of the flushing sterile saline is at least 5 ccm.

7. The catheter of claim 6, characterized in that a 5 ccm or larger syringe is used for flushing.

8. The catheter of claim 6, characterized in that injection caps are clamped to the proximal portion of the first lumen.

22. A venous line catheter system, said system having a catheter having at least one substantially elongate structure configured for establishing central venous access, said structure having a proximal portion and a distal portion and defining at least a first lumen in communication with the exterior of the elongate structure at said proximal and distal portions, and at least one heat exchange element extending at least along the distal portion adapted to effect heat exchange with the central venous system, characterized by a pump feeding heating/cooling agent at a flow rate in a range of 150 – 450 milliliters per minute through the heat exchange element.

23. The catheter system of claim 22, characterized in that the flow rate is about 240 milliliters per minute.

24. The catheter system of claim 22, characterized in that the temperature of the heating agent is between 38°C and 43°C.

25. The catheter system of claim 22, characterized in that the temperature of the cooling agent is between 1°C and 5°C.

26. The catheter system of claim 22, characterized in that the heat exchanging element is a balloon.

27. The catheter system of claim 26, characterized in that the balloon length is about 55-60 mm.

28. The catheter system of claim 22, characterized in that the heat exchanging element comprises a plurality of balloons.

29. The catheter system of claim 28, characterized in that the balloon length is about 55-60 mm.

30. The catheter system of claim 28, characterized in that three balloons are disposed in a consecutive order, a first balloon having a diameter of approximately 8-12 mm, a second balloon having a diameter of approximately 5-9 mm, and a third balloon having a diameter of approximately 4-6 mm.

31. The catheter system of claim 26, characterized in that the wall thickness of the balloon is between 35 μm and 70 μm.

32. The catheter system of claim 22, characterized in that the material from which the balloon is made is selected from the group: urethane, nylon, PE and PET.

33. The catheter system of claim 22, characterized in that the heat conductivity of the balloon is 0.1 to 1.5 Watt per meter x Kelvin.

34. The catheter system of claim 22, characterized in that the heating/cooling agent is a sterile saline.

APPENDIX B - EVIDENCE

None (this sheet made necessary by 69 Fed. Reg. 155 (August 2004), page 49978.)

APPENDIX C - RELATED PROCEEDINGS

None (this sheet made necessary by 69 Fed. Reg. 155 (August 2004), page 49978.)